REMARKS

This responds to the Office Action mailed on February 7, 2006, and the references cited therewith.

Claims 46-47 are canceled. As a result, claims 1-45 are now pending in this application. However, the Examiner has withdrawn claims 1-39 from consideration in view of the restriction requirement. Thus, claims 40-45 are under consideration.

Claim 40 has been amended. The phrase "a reactive oxygen species" in claim 40 has been replaced by the term "ozone," and the phrase "to thereby generate ozone to inhibit the growth of a bacterium" has been added to claim 40. Support for use of ozone in the method of the invention can be found throughout the specification and claims as originally filed, for example, in the Examples (see, e.g., Example III, at pages 85-90. Similarly, the term "microbe" has been deleted from claim 40 and the term "bacterium" has been used instead. Support for inhibiting bacterial cell growth in the method of the invention can be found throughout the specification and claims as originally filed, for example, in the Examples (see, e.g., Example III). In addition, claim 40 has been amended to include the following language: the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria. Support for this subject matter can be found throughout the specification and claims as originally filed, for example, at page 82, line 29 to page 83, line 1.

In addition, Applicant has corrected minor typographical errors in the specification and has requested has provided a substitute specification herewith.

Applicant submits that no new subject matter has been added to the application.

Affirmation of Election

As provisionally elected by Applicant's representative, Robin A. Chadwick, on November 7, 2005, Applicant elects to prosecute the invention of Group III (claims 40-47). The Examiner has withdrawn claims 1-39 from consideration.

Priority

The Examiner has refused to grant priority to 60/232,702, 60/235,475, 60/426,245, 60/315,906 and PCT/US01/29165 on the grounds that the subject matter of claims 40-47 has allegedly not been previously recited in the other applications.

Applicant submits that some of these applications do support methods of generating a reactive oxygen species to inhibit growth of a microbe.

For example, U.S. Ser. No. 60/315,906, filed August 29, 2001, provides the following support for such methods:

> The methods of this invention provide 1) for the production of oxidants when their production is warranted, such as in promoting wound healing, lysing bacteria, eliminating viruses, targeting cancer cells for oxidant-induced lysis and the like processes... For example, one may want to use antibody mediated hydrogen peroxide production to increase the local concentration of hydrogen peroxide to combat a bacterial infection in a wound. Here, an antibody could be used in conjunction with a sensitizer that would create singlet molecular oxygen. The antibody would generate hydrogen peroxide from the singlet molecular oxygen produced by the sensitizer and would cause a localized increase in the hydrogen peroxide concentration.

U.S. Ser. No. 60/315,906, page 9, lines 12-24.

> Additional therapeutic methods based on using an antibody that is capable of generating hydrogen peroxide from singlet oxygen are 1) for inhibiting proliferation of a cancer cell, 2) for targeting and killing a cancer cell in a patient where the antibody recognizes and immunoreacts with an antigen expressed on the cancer cell,... 4) for enhancing the bactericidal effectiveness of a phagocyte in a subject...

U.S. Ser. No. 60/315,906, page 18, lines 2-15; see also, U.S. Ser. No. 60/315,906, pages 15-18. Similar teachings are provided in the corresponding PCT application Ser. No. PCT/US01/29165 (filed Sep. 17, 2001) at page 19, lines 21-31; and page 30, line 5 to page 35, line 1. Therefore, Applicant submits that the present application and claims are supported by the U.S. Ser. No. 60/315,906, and PCT application Ser. No. PCT/US01/29165 disclosures and that Applicant is entitled to claim priority to the August 29, 2001 filing date of U.S. Ser. No. 60/315,906.

In addition, U.S. Ser. No. 60/426,245, filed November 14, 2002, provides data showing that antibodies can kill bacteria (see Fig. 14 and the Examples, especially Example 3). Therefore, Applicant does not understand why the Examiner asserts that the present claims are

not entitled to claim benefit of the filing data of U.S. Ser. No. 60/426,245 (filed November 14, 2002).

Therefore, Applicant asserts that the present claims are entitled to claim priority to at least the filing dates of U.S. Ser. No. 60/315,906 (Aug. 29, 2001), PCT application Ser. No. PCT/US01/29165 (Sep. 17, 2001) and U.S. Ser. No. 60/426,245 (November 14, 2002).

§112 Rejection Written Description Rejection of the Claims

Claims 40-47 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking adequate description or enablement. According to the Examiner, the claims are overly broad in that they are drawn to all microbes.

To satisfy the written description requirement, Applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he was in possession of the invention, and that the invention, in that context, is whatever is now claimed. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), and see M.P.E.P. § 2163.02.

Claim 40 is drawn to a method of generating ozone to inhibit the growth of a bacterium comprising contacting the microbe with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen ($^1O_2$) to thereby generate ozone to inhibit the growth of a bacterium, wherein the source of singlet oxygen is not covalently attached to the antibody and the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria.

Applicant submits that methods of inhibiting bacterial growth are clearly enabled by the specification (see, e.g., the Examples). Moreover, the claims are not drawn to methods involving all microbes. Applicant respectfully requests withdrawal of this rejection of claims 40-47 under 35 U.S.C. § 112, first paragraph.

§112 Rejection Indefiniteness Rejection of the Claims

Claims 40-47 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. According to the Examiner, the claims should contain a step correlating the contacting step of the claims with the generation of a reactive oxygen species.

Applicant submits that indefiniteness depends on whether one of skill in the art would understand the scope of the claim when the claim is read in light of the specification. *North American Vaccine Inc. v. American Cyanamid Co.*, 7 F.3d 1571, 28 USPQ2d 1333 (Fed. Cir.

1993). If the claims read in light of the specification reasonably apprise those skilled in the art of the scope of the invention, § 112 demands no more. *Miles Laboratories Inc. v. Shandon, Inc.*, 997 F.2d 870, 27 USPQ2d 1123 (Fed. Cir. 1993).

Claim 40 is drawn to a method of generating ozone to inhibit the growth of a bacterium comprising contacting the microbe with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen ($^1O_2$) to thereby generate ozone to inhibit the growth of a bacterium, wherein the source of singlet oxygen is not covalently attached to the antibody and the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria.

Applicant submits that the phrase "to thereby generate ozone to inhibit the growth of a bacterium" clearly correlates the contacting step with the generation of a reactive oxygen species (ozone). Therefore, Applicant respectively requests withdrawal of this rejection under 35 U.S.C. § 112, second paragraph.

MPEP § 2172.01 Rejection of the Claims

Claims 40-47 were rejected under MPEP §2172.01 as allegedly lacking an essential step. According to the Examiner, the claims should also include use of light and a correlation step as described above.

MPEP §2172.01 states that a claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may be rejected under 35 U.S.C. 112, first paragraph, as not enabling. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

However, as also stated at MPEP §2172.01, a claim does not necessarily fail to comply with 35 U.S.C. 112, second paragraph where the various elements do not function simultaneously, are not directly functionally related, do not directly intercooperate, and/or serve independent purposes (citing *Ex parte Huber,* 148 USPQ 447, 448-49 (Bd. Pat. App. 1965)).

Applicant submits that addition of light is not necessarily an essential element. The present specification teaches that light can be used with a sensitizer but that it is not necessarily needed in all instances. For example, the specification (page 23, lines 9-11) teaches the following:

> Examples of molecules that can generate singlet oxygen *without the need for other factors or inducers* include, but are not limited to,

> endoperoxides. In some embodiments, the endoperoxide employed can be an anthracene- 10-dipropionic acid endoperoxide. (Emphasis added.)

Thus, sources of singlet oxygen are available that do not relay on light to induce the formation of singlet oxygen. Hence, addition of light is not an essential step. Moreover, in many instances visible light can be used in the methods of the invention and patients are frequently exposed to visible light, for example, by walking outside or by turning on a light.

Therefore, addition of light is not necessarily an essential element and Applicant requests withdrawal of this rejection under MPEP §2172.01.

§102 Rejection of the Claims

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9th Cir. 1981).

Moreover, an anticipation rejection that is based on inherency must be supported by factual and technical grounds establishing that the inherent feature must flow as a necessary conclusion, not simply a possible conclusion, from the teaching of the cited art. *Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Int. 1990); *In re Oelrich*, 666 F.2d 578, 212 U.S.P.Q. 323, 326 (C.C.P.A. 1981).

Claim 40 is drawn to a method of generating ozone to inhibit the growth of a bacterium comprising contacting the microbe with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen ($^1O_2$) to thereby generate ozone to inhibit the growth of a bacterium,

wherein the source of singlet oxygen is not covalently attached to the antibody and the source of singlet oxygen would not, on its own, inhibit the growth of the bacteria.

Devanathan

Claims 40-43 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Devanathan et al. (*Proc. Nat'l. Acad. Sci. USA*, Vol. 87, pp. 2980-2984, April 1990 (Devanathan)). According to the Examiner, Devanathan discloses fluorescein isothiocyanate-conjugated antibodies that are converted into targeting agents for anti-bacterial therapy.

Applicant submits that Devanathan is limited to a teaching that iodination of fluorescein isothiocyanate-conjugated antibodies makes these conjugates phototoxic. Moreover, as stated by the Examiner, the photodynamic sensitizer used by Devanathan must be phototoxic (Office Action at 8 (Feb. 7, 2006)).

In contrast, the source of singlet oxygen used in the methods of the invention would not, on its own, inhibit the growth of the bacteria.

Applicant respectfully requests withdrawal of this rejection of claims 40-43 under 35 U.S.C. § 102(b) with respect to Devanathan.

Berthiaume

Claims 40-43 and 45 were rejected under 35 U.S.C. § 102(b) for anticipation by Berthiaume et al. (*Biotechnology*, Vol. 12, pp. 703-706, July 1994 (Berthiaume)). According to the Examiner, Berthiaume teaches antibody-targeted photolysis of bacteria *in vivo*.

Applicant submits that Berthiaume is limited to disclosure of photolysis of bacteria using tin (IV) chlorin e,-monoclonal antibody conjugates, where the antibody acts only as a delivery vehicle and, according to Berthiaume, has no role in actually killing the bacteria. Moreover, Berthiaume is limited to tin (IV) chlorin e,-monoclonal antibody conjugates, and provides no disclosure or teaching of a composition consisting of an antibody with a source of singlet oxygen that is not covalently attached to the antibody.

Thus, Berthiaume does not disclose or teach a method of generating ozone to inhibit the growth of a bacterium comprising contacting the microbe with (i) an antibody that can bind to the bacterium and (ii) a source of singlet oxygen ($^1O_2$) to thereby generate ozone to inhibit the

growth of a bacterium, wherein the source of singlet oxygen is not covalently attached to the antibody.

Moreover, Berthiaume provides no disclosure or teaching of a source of singlet oxygen that would not, on its own, inhibit the growth of the bacteria.

Applicant respectfully requests withdrawal of this rejection of claims 40-43 and 45 under 35 U.S.C. § 102(b).

Wentworth

Claims 40-42 and 44-47 were rejected under 35 U.S.C. § 102(b) for anticipation by Wentworth et al. (*PNAS*, Vol. 97, No. 20, pp. 10930-10935, Sept. 26, 2000 (Wentworth)), in light of the Scripps Press Release of November 14, 2002.

Applicant submits that this article by Wentworth is not prior art to the present application and claims because the present application, among other things, derives benefit of the filing date of U.S. Patent Application Ser. No. 60/426,242, filed November 14, 2002. Note that the Ser. No. 60/426,242 application is not amongst the priority claims questioned by the Examiner above. In addition, Applicant asserts that the present claims are entitled to claim priority to at least the filing dates of U.S. Ser. No. 60/315,906 (Aug. 29, 2001), PCT application Ser. No. PCT/US01/29165 (Sep. 17, 2001) and U.S. Ser. No. 60/426,245 (November 14, 2002).

Accordingly, Applicant respectfully submits that this rejection of claims 40-42 and 44-47 under 35 U.S.C. § 102(b) cannot maintained and requests withdrawal thereof.

CONCLUSION

Applicant respectfully submits that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney at (516) 795-6820 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

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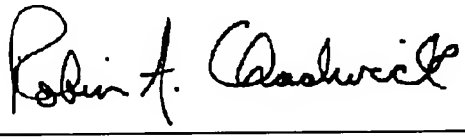
Date May 8, 2006

By 

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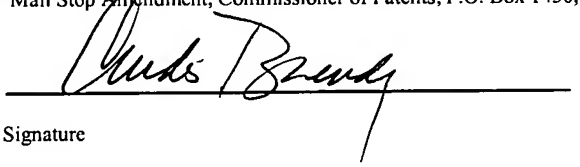

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